

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: <i>Ethicon Wave 11 cases listed in Exhibit A to Plaintiffs' Motion</i>	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION
TO EXCLUDE THE GENERAL CAUSATION OPINIONS
OF DEFENSE EXPERT RICHARD WASSERMAN, M.D.**

This Court should exclude the general opinions of Richard Wasserman, MD, FACOG, FPMRS, as his own testimony indicates that he does not believe that the opinion of a single expert is at all helpful. He also indicated during his deposition testimony that he was “making it up as I go.” Dr. Wasserman is a new expert who clearly did not take the process seriously, and by his own admission, his opinions have no value to the jury. Therefore, his opinions should be excluded under Rule 702 and the standard first announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

Alternatively, this Court should exclude the following opinions stated in Dr. Wasserman's report, as he is not qualified to give these opinions and/or they are not supported by a reliable methodology, as the *Daubert* standard requires:

- Any discussion of the physical properties of the Polypropylene mesh to support his opinion that the TVT, TVT-O, TVT-Abbrevio, and TVT-Exact are “safe and

effective” products. (*See* Wasserman Report, attached to the Motion as Exhibit B, at p. 13).

- Any opinions about the alleged lack of foreign body reaction caused by the mesh or cytotoxicity of the mesh. (*See id.* at 14).
- Any opinions that the mesh has not suffered particle loss, fraying, curling, or roping of the mesh. (*See id.*).
- Any opinions that the mesh does not degrade in the body. (*See id.*).
- Any opinions that there is no clinically significant difference between using laser-cut mesh and using mechanically cut mesh. (*See id.* at 16).
- Any opinions about the warnings in the Instructions for Use (“IFU”). (*See id.* at 17).

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, “the district court must decide whether the expert has ‘sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.’” *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents “scientific

knowledge,” meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert’s opinions “fit” the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony “must be supported by appropriate validation—i.e., ‘good grounds,’ based on what is known. In short, the requirement that an expert’s testimony pertain to ‘scientific knowledge’ establishes a standard of evidentiary reliability.” *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, “the factors discussed in *Daubert* were neither definitive, nor exhaustive.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses’ “principles and methodology, not on the conclusions that they generate.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because “*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder.” *Cavallo*, 100 F.3d at 1158.

ARGUMENT

This Court should exclude Dr. Wasserman's testimony because his opinions are, by his own admission, not helpful to the jury. Alternatively, he does not have the qualifications or knowledge, and/or has not used reliable methods to support several of his specific opinions, as discussed below.

I. If Dr. Wasserman's testimony is to be believed, then the testimony of one person has no value. If he does not believe that his testimony would be helpful to the jury, then the Court should reach the same conclusion and exclude him.

Dr. Wasserman is a urogynecologist and pelvic surgeon based in Las Vegas, Nevada. (Wasserman Report, Ex. B, at 2). He has written an expert report on four of Ethicon's devices used to treat stress urinary incontinence ("SUI")—the TVT, TVT-O, TVT-Exact, and TVT-Abbrevio. (*Id.*). None of his opinions separate out those four devices in any way, and he treats them all as being functionally equivalent, despite their differences. (Wasserman Dep. Rough Draft, attached to Motion as Exhibit C, at 41:1-11, 43:3-9).¹ His deposition on August 12, 2019, was his first deposition as an expert witness. (*Id.* at 18:8-13).

Dr. Wasserman made it clear during his deposition that he does not trust the opinions of any one individual. For instance, he testified that "when I review material for forming my opinion, I would not base it on the one specific individual's conclusions." (*Id.* at 30:22-31:4).

That answer led to the following exchange on the topic:

Q. What if we're talking about sworn testimony from an engineer, a person who worked on the design of the TVT products? Is your answer the same with regard to testimony as it is to documents?

¹ Because Dr. Wasserman was only deposed three days before the filing deadline for this Motion, Plaintiffs have only a rough draft of the deposition, which came to Plaintiffs' counsel in a TXT file but has been converted to PDF. Page number references are to the number in the **top-right corner** of each page. There are also page numbers at the bottom-center of each PDF page, but Plaintiffs are not using those numbers in the citations. In some places, the transcript has been lightly edited to correct what appear to be typographical errors.

MR. KOOPMANN: Object to form.

THE WITNESS: Yes, I would agree. I think they are just the opinion of one individual. So I don't put too much weight on that.

(*Id.* at 31:21-32:3).

Throughout his deposition testimony, Dr. Wasserman emphasized the fact that it is improper to base any conclusions on the opinions of a single individual. Dr. Wasserman even went so far as to say he would disregard the opinions of top officials at Ethicon. For instance, he was asked about the testimony of former Ethicon medical director David Robinson, who has testified that the mesh causes a chronic foreign body reaction²:

Q. Have you reviewed the testimony of Dr. David Robinson in formulating your opinions in this case?

A. David Robinson? Again, I'm terrible with names. That one does not ring a bell.

Q. Okay. I'll represent to you that he was a medical director with Ethicon between 2005 and 2010. Were you aware that he testified as the medical director in charge of the TVT products that the TVT mesh will undergo a chronic foreign body reaction for as long as it's implanted in the body?

A. Like I said, that's the opinion of one person. We've talked about that earlier

Q. It's the opinion of one person who happened to be the person that Ethicon and Johnson & Johnson selected to be their medical director for the TVT products, right?

A. That's correct. Actually, you are telling me that's correct. I don't remember David Robinson.

Q. Yes.

A. When I think of David Robinson I think of the guy that used to play for the [San Antonio] Spurs, but it's definitely not him.

² That testimony is attached to the Motion as Exhibit D. (*See Robinson Dep.*, Sept. 11, 2013, at 971:6-16).

(*Id.* at 239:12-240:11).

Dr. Wasserman also expressed disagreement with Dr. Martin Weisberg, who testified as Ethicon's corporate representative with regard to warnings (his warnings issues are discussed in more detail below). (*See id.* at 129:1-134:17). Later, Dr. Wasserman stated that he would consider the opinions of Ethicon's medical directors to be of low value. (*Id.* at 273:24-274:4).

He then testified as follows:

Q. Does that mean that your opinions as an individual are also of low value?

A. These are my opinions.

Q. We talked about —

A. They are valuable to me.

(*Id.* at 274:5-9). Of course, testimony valuable to only Dr. Wasserman should not be permitted.

In addition to de-valuing his own testimony, Dr. Wasserman testified during his deposition that he was “making it up as I go,” that he was “kind of guessing about these things,” and that “I’m just kind of making stuff up, and I’m sorry about that.” (*Id.* at 234:16-235:1, 236:2-5). Clearly, these are not the comments of an expert who is taking the scientific process seriously.

As demonstrated by his deposition, Dr. Wasserman does not have any specialized experience or knowledge that might compensate for these other issues. Dr. Wasserman claims to rely on his clinical experience in reaching many of his opinions, but he does not currently use the products on which he is opining. (*Id.* at 49:22-24). He says this is because none of the several hospitals where he has privileges to perform surgery carry Ethicon's products. (*Id.* at 49:25-50:7). Dr. Wasserman has not published any peer-reviewed articles on mesh slings or polypropylene mesh. (*Id.* at 93:4-7, 102:15-20). He also was unable to define the “standard of

care,” and he offered the contradictory testimony that physicians using the Burch procedure are “performing outside the standard of care,” but are “absolutely not” committing malpractice. (*Id.* at 96:22-97:16).

For these reasons, this Court should exclude Dr. Wasserman entirely from testifying. His testimony simply does not meet the *Daubert* requirement that the testimony must be helpful to the jury. *Dorsey*, 45 F.3d at 813. He personally places no value on the opinions of individuals, and yet by putting him on the stand, Ethicon would be asking the jury to place value on his individual opinions as an expert. It is a complete contradiction. In addition, as noted above, he admitted that he was making up his testimony as he went along. That testimony is enough for this Court to exclude Dr. Wasserman entirely.

II. Dr. Wasserman does not have the necessary qualifications to opine about the physical properties of the mesh, and his testimony further shows that his opinions on this subject are not reliable.

If this Court does not exclude Dr. Wasserman entirely, it should exclude several of his individual opinions, beginning with his opinions regarding the physical properties of the mesh. More specifically, this Court should prohibit Dr. Wasserman from offering all of the following opinions, as his deposition indicates that he is not qualified and does not have a reasonable evidentiary foundation to opine about these topics, which are addressed in his report:

- Any discussion of the physical properties of the Polypropylene mesh to support his opinion that the TVT, TVT-O, TVT-Abbrevio, and TVT-Exact are “safe and effective” products. (*See* Wasserman Report, Ex. B, at 13).
- Any opinions about the alleged lack of foreign body reaction caused by the mesh or cytotoxicity of the mesh. (*See id.* at 14).

- Any opinions that the mesh has not suffered particle loss, fraying, curling, or roping of the mesh. (*See id.*).
- Any opinions that the mesh does not degrade in the body. (*See id.*).

All of these opinions relate to the physical properties of the mesh, and Dr. Wasserman has not demonstrated the necessary expertise to offer opinions that would be helpful to the jury. Dr. Wasserman is not a chemical engineer. (Wasserman Dep., Ex. C, at 103:19-25). He is not a surgical pathologist. Though he claimed to be an expert in surgical pathology, Dr. Wasserman admitted that he has never sought employment as a surgical pathologist, has never received compensation as a surgical pathologist, and did not do a fellowship in surgical pathology. (*Id.* at 104:21-105:14). He also acknowledged that he rarely reviews histopathologic slides. (*Id.* at 105:21-106:3). Dr. Wasserman has no professional background in polymer chemistry. (*Id.* at 106:17-20). He claimed to have some knowledge on the topic, but was unable to identify the type of polypropylene used in the product that he currently uses in mesh surgery, or in Ethicon's products for that matter. (*Id.* at 109:1-15). Dr. Wasserman has not done bench research or lab research on polypropylene products. (*Id.* at 112:9-14). He has no published opinions on polypropylene. (*Id.* at 113:25-114:3). He is not an engineer, and he has never worked on the design of a medical device. (*Id.* at 154:21-25). Dr. Wasserman has not done any testing regarding the stiffness of the mesh. (*Id.* at 214:18-22).

Plaintiffs recognize that this Court has allowed some experts to testify about the physical properties of mesh, despite not having these specialized backgrounds, where the expert's training, clinical experience, and testimony demonstrate specialized knowledge in this area. *See, e.g., Foreman v. Bos. Sci. Corp.*, No. 2:13-CV-15591, 2016 WL 3039895, at *7 (S.D.W. Va. May 27, 2016) (permitting Dr. Bruce Rosenzweig's testimony on these topics). However, the

Court has been more skeptical of such testimony when there is an absence of support for the expert's opinions, beyond simply clinical observations—or the lack thereof. *See id.* at *14 (reserving ruling on motion where expert's opinions on physical properties of mesh were supported only by non-specific clinical experience and a literature review). And then, where deposition testimony has revealed further flaws in expert's qualifications and/or methodology, this Court has taken the additional step of excluding the expert entirely from opining on the physical properties of the mesh. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 580 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014).

Here, Dr. Wasserman's deposition testimony reveals a lack of qualifications or knowledge on the topic of the physical properties of the mesh. Dr. Wasserman continued to insist that all polypropylene meshes perform the same, regardless of the type of polypropylene used, leading to this exchange:

Q. So it's fair to say that you don't know if the polypropylene – different polypropylenes between the TVT family of products and the Caldera and the Boston Scientific, you don't know, as you sit here today, if they have different additives or ingredients between the polypropylenes, right?

A. They probably do.

(Wasserman Dep., Ex. C, at 111:3-9). Clearly, he knows nothing about the additives that go into the polypropylene mesh.

Dr. Wasserman also had no support for his opinion that the Prolene material used in Ethicon's meshes is safe and effective. He relied on the affidavit of an Ethicon employee—clearly a biased source. (*Id.* at 205:2-19). When asked if he had any other support for the opinion that Prolene polypropylene is safe and effective, Dr. Wasserman responded: "I'm trying to think. Nothing is coming offhand that – describing Prolene polypropylene, but I do believe it is Prolene polypropylene, but nothing is jumping out right now." (*Id.* at 206:17-207:1).

In addition, Dr. Wasserman had strange testimony about particle loss and degradation, which was not backed by any reliable foundation. For instance, he was asked about physician reports that sometimes the TVT device would arrive with particles already having fallen off, sitting loose in the box. He testified as follows:

Q. Okay. While you state that you have seen no evidence in your practice or published literature indicating that particle loss occurs in the body, would you agree with me that if particle loss is occurring in the package, in the blister package before you even place it in the patient, that that's evidence that the mesh is at least physically degrading?

MR. KOOPMANN: Object to form.

THE WITNESS: No.

BY MR. FAES:

Q. So, you don't consider particle loss in a blister package to be evidence of physical degradation of the mesh?

A. I do not, but again, you are throwing out these hypotheticals at me and I'm going, you know, I'm kind of making it up as I go along, honestly.

(*Id.* at 234:5-21).

Another of Dr. Wasserman's opinions regarding the physical properties of the mesh is that the mesh is not cytotoxic. (Wasserman Report, Ex. B, at 14). Yet, Dr. Wasserman had no good answer for a question about testing by Ethicon that showed that the mesh is, in fact, cytotoxic. As with his responses to many other questions, he simply falls back on general statements about his clinical experience and the scientific literature:

Q. As an expert for Ethicon and Johnson & Johnson, who is giving the opinion that the mesh is not cytotoxic, how do you explain the four separate tests that Ethicon and Johnson & Johnson did that showed that the TVT mesh was markedly or moderately cytotoxic?

A. Which ones are you talking about?

Q. First of all, are you aware –

A. Yes.

Q. -- that there have been four separate tests?

A. Yes. In the 90s, I don't really place too much value on those based upon the current body of evidence which says that it is not cytotoxic.

Q. Are you aware of any cytotoxicity testing that Ethicon and Johnson & Johnson has done after the launch of the TVT mesh in the United States specifically with regard to cytotoxicity?

A. I'm sure I've read a couple of those as well.

Q. You believe you have seen cytotoxicity tests done on the TVT mesh after 1998?

A. I'm trying to think.

Q. I'd sure like to see them if they are out there.

A. You know, it's not jumping out right this second. Everything is kind of meshing in my head.

(Wasserman Dep., Ex. C, at 246: 8-247:7).

Again, Dr. Wasserman's testimony shows that he has no solid foundation for his opinions about cytotoxicity. He was unable to explain away the evidence from Ethicon's own testing that the mesh is, in fact, cytotoxic.

In combination, all of this testimony shows that Dr. Wasserman does not have the qualifications to testify about the physical properties of the mesh, and that any such testimony would not be the product of reliable principles and methods. He does not understand degradation. He ignores the evidence about particle loss. He ignores the evidence about cytotoxicity. For these reasons, the Court should exclude the opinions laid out in the bullet points above, all of which deal with the physical properties of the mesh.

III. This Court should exclude Dr. Wasserman's opinion that laser-cut mesh and mechanically cut mesh have similar complication rates, as that opinion is based largely on wholly unsupported observations from his own practice.

This Court should further exclude Dr. Wasserman's opinion that there is no clinical difference between mechanically cut and laser-cut mesh. (*See* Wasserman Report, Ex. B, at 16). This opinion is based in large part on Dr. Wasserman's own belief about complication rates in his practice, and yet his testimony shows that he has not taken any steps to reliably measure the complication rates in his practice.

The Court has excluded similar testimony in the past. *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4582231, at *3 (S.D. W. Va. Sept. 1, 2016) (excluding testimony about complication rates in the practice of Ethicon expert Michael Woods, and noting that "Dr. Woods's estimated complication rates lack any vestige of a scientifically-applied methodology"). The same reasoning applies here, as Dr. Wasserman has no basis for concluding that the complications rates with laser-cut mesh and mechanically cut mesh are similar in his practice. This is particularly true given that he has **not once** reported a complication to the FDA.

Dr. Wasserman testified that there are "two reasons" why he does not believe there is any difference between the complication rates in laser-cut and mechanically cut mesh:

- A. One is that in my patient population there has been no difference in complications associated with them, and the literature does support that as well, that there's equivalence between the laser cut versus the mechanically cut. I don't think it makes one difference.
- Q. Okay. But with regard to your own clinical practice and what you have seen, you would agree with me that you haven't done any formal analysis of complication rates between a laser cut mesh and mechanically cut mesh?
- A. I have not done a formal analysis.

Q. You couldn't for example, give me a number of how many mechanically cut mesh slings you've done versus laser cut mesh slings; right?

A. I cannot quantify which I have done most. I have done both of them, and I find the complication rates between laser cut and mechanically cut are equivalent. The literature also supports that as well.

(Wasserman Dep., Ex. C, at 176:9-177:3). Thus, Dr. Wasserman is unable to support his opinion about complication rates with anything more than general references to his practice and to "the literature."

The references to complication rates in his practice are further suspect due to his failure to report complications. When asked if he had reported a complication to the FDA on any of the 50-plus instances where he "surgically revised complications from pelvic mesh," Dr. Wasserman testified that he had never done so. (*Id.* at 146:14-18). He added this testimony:

Q. Do you consider a case where you have to go to the operating room to surgically revise or excise a surgical mesh to be a serious complication?

A. I do not.

Q. Do you know whether or not the FDA considers that to be a serious complication?

A. They may consider it to be a serious complication if they need to return to the operating room. However, it's an easily revisable complication.

(*Id.* at 147:23-148:6). Because Dr. Wasserman has not been reporting even complications requiring surgery—and, in fact, does not really consider them to be complications—his testimony about complication rates "lack[s] any vestige of a scientifically-applied methodology." Thus, it should be excluded.

At the very least, his opinions about his personal complication rates should be excluded. But those opinions also taint his opinion comparing laser-cut mesh complication rates with mechanically cut mesh complication rates, so that opinion should be excluded as well. Besides

Dr. Wasserman's personal experience, the only additional basis for that opinion was a general reference to "the literature." If that were sufficient, no opinion would ever be excluded under *Daubert*. Thus, this Court should preclude Dr. Wasserman from offering any testimony comparing the complication rates for laser-cut mesh and mechanically cut mesh.

IV. Dr. Wasserman has no expertise in warnings, he does not personally rely on the Instructions for Use, and his view of the information that needs to be in the IFU differs from the FDA's. Thus, he should be excluded from giving any testimony regarding warnings or the IFU.

Finally, this Court should have little trouble in concluding that Dr. Wasserman should not be permitted to opine about warnings. (*See* Wasserman Report, Ex. B, at 17). He does not believe that the IFU have any value to physicians, he does not rely on them, and he overtly disagrees with the FDAs standard for what should go into the warnings.

Generally, this Court does not permit urogynecologists or urologists to testify as to the sufficiency of warnings, unless they demonstrates some additional basis for their expertise, beyond the use of warnings in their practice. *See, e.g., In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2017 WL 1175399, at *4 (S.D. W. Va. Mar. 29, 2017) ("While an expert who is a urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU.").

Dr. Wasserman should at least be similarly limited, as there is nothing in his report or deposition to indicate that he has any kind of specialized expertise with regard to product warnings. He has not written an IFU for a medical device, nor has he participated in the drafting of warnings for either a medical device or a drug. (Wasserman Dep., Ex. C, at 119:20-120:17). But even beyond that, Dr. Wasserman is the rare expert who should be excluded from opining

about warnings **at all**, given his antipathy for reliance on the IFU, and his lack of understanding of what the FDA requires of medical device manufacturers.

Though Dr. Wasserman claimed to be an expert in “how the FDA works and their function,” he did not know the classification for the TVT family of products. (*Id.* at 114:6-12, 115:1-5). He also claimed to be an expert on warnings. (*Id.* at 115:25-116:4). However, this is an odd statement, given that he does not rely on warnings in his practice.

When asked about testimony by Ethicon medical director Piet Hinoul, stating that surgeons should be able to rely solely on the IFU to learn about the adverse events associated with the device, Dr. Wasserman replied: “I don’t think that that is the source. I think that we as clinicians and as surgeons, we get our information regarding complications from any type of a procedure, we get them mostly from the literature. We get them from going to meetings. We get them from our societies.” (*Id.* at 118:13-119:1).

When asked to recite the industry standards that govern warnings on medical devices, Dr. Wasserman testified:

- A. The standards? Again, there’s a list of standards that are involved with warnings and regulations, and offhand I cannot repeat that list to you off the top of my head, but I’m familiar with it and I can provide it for you, if you like.

(*Id.* at 116:12-18). Remarkably, when he was given the answer to the test, Dr. Wasserman still disagreed:

- Q. Do you agree with me that if there’s a reasonable association between a medical device and an adverse event, that a company must disclose that information in the IFU or instructions for use?

MR. KOOPMANN: Object to form.

THE WITNESS: Yeah, again, I don’t think that the IFU is the right avenue to disclose these types of ...

Q. Do you know whether or not there's any guidance from the FDA or elsewhere that says that if there's a reasonable association between a medical device and an adverse event, that the company must disclose that information?

A. There are guidelines out there, yes.

Q. Would you agree with me that if a company, medical device company becomes aware of a reasonable association between a medical device and an adverse event and doesn't disclose that information in the IFU, that they are not following the guidelines?

MR. KOOPMANN: Same objection.

THE WITNESS: The – disclosing these within the IFU, I don't think that that's the most effective way to disclose these types of complications. So the IFU does have a section for adverse events, and within reasonable – within reason, you can put the adverse events in the IFU, but to put all complications associated with a device is a bit much.

(*Id.* at 149:23-151:8). When counsel asked again if he was stating the proper FDA guideline—clearly, a general question—Dr. Wasserman responded that he would need to know more about the specific device to be able to answer. (*Id.* at 152:4-14).

Plaintiff's counsel **was** reciting FDA guidelines for adding warnings information to the IFU. According to the FDA's "Blue Book" guidance document, under the header of "V. Warnings," manufacturers are instructed to: "Include an appropriate warning if there is a reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved." (*FDA Device Labeling Guidance #G91-1 (blue book memo)*, March 9, 1991, attached to Motion as Exhibit E, at p. 4). The FDA guidance also has this requirement under the heading of "VIII. Adverse Reactions": An adverse reaction is an undesirable effect, reasonably associated with the use of the device, that may occur as part of the

effect of the device or may be unpredictable in its occurrence.” (*Id.* at p. 5). Further, “[t]his section includes all adverse reactions reasonably associated with the use of the device.” (*Id.*).

Because Dr. Wasserman attaches little importance to the warnings in the IFU, and because he did not understand the standards applied by the FDA for when it is necessary to add information to the IFU, he should be precluded from giving any testimony regarding product warnings.

CONCLUSION

For all of these reasons, this Court should preclude Dr. Wasserman from testifying in this litigation. He admits that his testimony has little value, as he is only one person. He also admitted during his deposition that he was “making it up as I go,” and that he was “kind of guessing about these things.”

Alternatively, the Court should at least preclude Dr. Wasserman from offering the following opinions, as laid out above:

- Any discussion of the physical properties of the Polypropylene mesh to support his opinion that the TVT, TVT-O, TVT-Abbrevio, and TVT-Exact are “safe and effective” products.
- Any opinions about the alleged lack of foreign body reaction caused by the mesh or cytotoxicity of the mesh.
- Any opinions that the mesh has not suffered particle loss, fraying, curling, or roping of the mesh.
- Any opinions that the mesh does not degrade in the body.
- Any opinions that there is no clinically significant difference between using laser-cut mesh and using mechanically cut mesh.

- Any opinions about the warnings in the IFU.

Dated: August 15, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on August 15, 2019, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/Thomas P. Cartmell

Attorney for Plaintiffs